

COMMITTEE ON LEGISLATIVE RESEARCH
OVERSIGHT DIVISION

FISCAL NOTE

L.R. No.: 1926-03
Bill No.: HCS for HB 816
Subject: Drugs and Controlled Substances; Health Department; Health Care Professionals;
Pharmacy
Type: Original
Date: April 8, 2015

Bill Summary: This proposal establishes the Prescription Drug Monitoring Program Act.

FISCAL SUMMARY

ESTIMATED NET EFFECT ON GENERAL REVENUE FUND				
FUND AFFECTED	FY 2016	FY 2017	FY 2018	Fully Implemented (FY 2019)
General Revenue	\$0 or (More than \$7,100,000)	\$0	\$0	\$0
Total Estimated Net Effect on General Revenue	\$0 or (More than \$7,100,000)	\$0	\$0	\$0

ESTIMATED NET EFFECT ON OTHER STATE FUNDS				
FUND AFFECTED	FY 2016	FY 2017	FY 2018	Fully Implemented (FY 2019)
Total Estimated Net Effect on <u>Other</u> State Funds	\$0	\$0	\$0	\$0

Numbers within parentheses: () indicate costs or losses. This fiscal note contains 13 pages.

ESTIMATED NET EFFECT ON FEDERAL FUNDS				
FUND AFFECTED	FY 2016	FY 2017	FY 2018	Fully Implemented (FY 2019)
Total Estimated Net Effect on <u>All</u> Federal Funds	\$0	\$0	\$0	\$0

ESTIMATED NET EFFECT ON FULL TIME EQUIVALENT (FTE)				
FUND AFFECTED	FY 2016	FY 2017	FY 2018	Fully Implemented (FY 2019)
Total Estimated Net Effect on FTE				

☐ Estimated Net Effect (expenditures or reduced revenues) expected to exceed \$100,000 in any of the three fiscal years after implementation of the act.

ESTIMATED NET EFFECT ON LOCAL FUNDS				
FUND AFFECTED	FY 2016	FY 2017	FY 2018	Fully Implemented (FY 2019)
Local Government*	\$0	\$0	\$0	\$0

* Possible Transfers-in and expenses would net to \$0.

FISCAL ANALYSIS

ASSUMPTION

Due to time constraints, **Oversight** prepared a fiscal note for the original version of this bill without all of the agency responses. Oversight has since obtained the agency responses and upon review of those responses, believes the original fiscal note does not need to be updated. This fiscal note updates the original by providing agency responses as well as including changes for the current provisions of the proposal.

In response to another version of this proposal, officials from the **Office of Secretary of State (SOS)** provided the following response:

Each year, a number of joint resolutions that would refer to a vote of the people a constitutional amendment and bills that would refer to a vote of the people the statutory issue in the legislation may be considered by the General Assembly.

Unless a special election is called for the purpose, Joint Resolutions proposing a constitutional amendment are submitted to a vote of the people at the next general election. Article XII section 2(b) of the Missouri Constitution authorizes the Governor to order a special election for constitutional amendments referred to the people. If a special election is called to submit a Joint Resolution to a vote of the people, section 115.063.2 RSMo requires the state to pay the costs. The cost of the special election has been estimated to be \$7.1 million based on the cost of the 2012 Presidential Preference Primary.

The Secretary of State's office is required to pay for publishing in local newspapers the full text of each statewide ballot measure as directed by Article XII, Section 2(b) of the Missouri Constitution and Section 116.230-116.290, RSMo. The Secretary of State's office is provided with core funding to handle a certain amount of normal activity resulting from each year's legislative session. Funding for this item is adjusted each year depending upon the election cycle with \$1.3 million historically appropriated in odd numbered fiscal years and \$100,000 appropriated in even numbered fiscal years to meet these requirements. Through FY 2013, the appropriation had historically been an estimated appropriation because the final cost is dependent upon the number of ballot measures approved by the General Assembly and the initiative petitions certified for the ballot. In FY 2013, at the August and November elections, there were 5 statewide Constitutional Amendments or ballot propositions that cost \$2.17 million to publish (an average of \$434,000 per issue). In FY 2015, the General Assembly changed the appropriation so that it was no longer an estimated appropriation and the Secretary of State's office was appropriated \$1.19 million to publish the full text of the measures. Due to this reduced funding, the Secretary of State's office reduced the scope of the publication of these measures. In FY 2015, at the August and November elections, there were 9 statewide

ASSUMPTION (continued)

Constitutional Amendments or ballot propositions that cost \$1.1 million to public (an average of \$122,000 per issue). Despite the FY 2015 reduction, the Secretary of State's office will continue to assumed, for the purposes of this fiscal note, that it should have the full appropriation authority it needs to meet the publishing requirements. Because these requirements are mandatory, the SOS reserves the right to request additional funding to meet the cost of its publishing requirements if the Governor and the General Assembly again change the amount or continue to not designate it as an estimated appropriation.

Oversight has reflected in this fiscal note, the state potentially reimbursing local political subdivisions the cost of having this joint resolution voted on during a special election in fiscal year 2016. This reflects the decision made by the Joint Committee on Legislative Research, that the cost of the elections should be shown in the fiscal note. The next scheduled statewide primary election is in August 2016 and the next scheduled general election is in November 2016 (FY 2017). It is assumed the subject within this proposal could be on one of these ballots; however, it could also be on a special election called for by the Governor. Therefore, Oversight will reflect a potential election cost reimbursement to local political subdivisions in FY 2016.

In addition, the SOS stated many bills considered by the General Assembly include provisions allowing or requiring agencies to submit rules and regulations to implement the act. The SOS is provided with core funding to handle a certain amount of normal activity resulting from each year's legislative session. The fiscal impact for this fiscal note to the SOS for Administrative Rules is less than \$2,500. The SOS recognizes that this is a small amount and does not expect that additional funding would be required to meet these costs. However, the SOS also recognizes that many such bills may be passed by the General Assembly in a given year and that collectively the costs may be in excess of what the office can sustain with the core budget. Therefore, the SOS reserves the right to request funding for the cost of supporting administrative rules requirements should the need arise based on a review of the finally approved bills signed by the governor.

Oversight assumes the SOS could absorb the costs of printing and distributing regulations related to this proposal. If multiple bills pass which require the printing and distribution of regulations at substantial costs, the SOS could request funding through the appropriation process.

Officials from the **Department of Health and Senior Services (DHSS)** provide the following information:

§ 195.453.1 - Grants, Gifts and Donations:

This section of the proposal states, in part:

"...The department may apply for any available grants and shall accept any gifts, grants, or donations to develop and maintain the program. All funding for prescription drug monitoring program shall be provided exclusively by gifts, grants, and donations."

ASSUMPTION (continued)

The DHSS assumes none of the costs associated with a prescription drug monitoring system will be funded with General Revenue. Also, since the DHSS is not assured of any potential grant funding opportunities at this time, none of the prescription monitoring costs are assumed to be funded by grants. If DHSS receives a federal grant, these costs, or a portion of the costs would be covered by the federal grant. For fiscal note purposes, all costs of the prescription monitoring program (Sections 195.450 through 195.465 of the proposed legislation) are, therefore, assumed to be funded solely by gifts and donations deposited into the Donated Fund. At this time, the DHSS is not aware of any potential gifts for donations for this purpose.

Section B of the proposed legislation would submit the establishment of a prescription drug monitoring system to a vote of the people in November, 2016 and it would become effective when approved by the voters. As a result, DHSS assumes costs related to a prescription monitoring program would not commence until January 1, 2017 if the referendum is approved. However, if gifts, grants, or donations sufficient to fund the prescription monitoring program on an ongoing basis are not received, it is assumed the program would not be implemented.

§§ 195.450 through 195.465 - Drug Monitoring Program Act:

One Health and Senior Services Manager (\$39,980 annually) will be needed to perform the following duties:

- Draft a Request for Proposal to solicit bids for the required database. Once the contract is awarded, this individual will be needed on an ongoing basis to monitor the database contract and program, maintain ongoing communication with professional organizations regarding compliance with reporting requirements, and other state and local agencies and the public regarding the program;
- Coordinate with investigative management of the Bureau of Narcotics and Dangerous Drugs (BNDD) for enforcement activities and with law enforcement and regulatory agencies of Missouri and other states for sharing data and tracking outcomes;
- Develop rules, policies, and procedures for reporting by dispensers and access to data by authorized parties;
- Provide technical assistance to program participants on matters relating to the program;
- Supervise subordinate staff involved in program implementation;
- Design and prepare reports of program data and review data collected to determine trends;
- Provide required educational programs regarding the Prescription Drug Monitoring Program required in Section 195.468; and
- Develop reports to the General Assembly regarding the pilot project on prescription fraud (Section 195.477).

ASSUMPTION (continued)

One Health Program Representative I (\$30,672 annually) will:

- Provide support to the program;
- Respond to inquiries and requests for database reports received;
- Perform coordination of communication with other agencies and the public, and maintenance of memoranda of understanding for data sharing;
- Assist practitioners in obtaining access to the reporting subsystem of the program;
- Generate and e-mail or generate, print, and fax reports as requested by authorized individuals and agencies that cannot access this information via the internet; and
- Respond to telephone inquiries regarding the program and answer the toll-free number established for reporting prescription fraud (Section 195.471).

One Investigative Manager (\$39,980 annually) will:

- Review database information;
- Assign and supervise investigations;
- Assist the manager in operating the database and supervise investigative staff; and
- Assist the manager in providing the required educational courses (Section 195.468).

The above three positions will be hired on January 1, 2017 if funding from gifts and donations is available.

Three Investigator II positions will be needed to respond to complaints and conduct investigations. These positions are assumed to be telecommuters. These positions will be hired on January 1, 2017. This fiscal note assumes minimal staffing and the review and referral of only the most serious issues identified in the dispensation information. Additional staff would be required to increase the level of review and investigation.

§195.453.5 - Dispenser reimbursements

Section 195.453.5 of the proposed legislation requires DHSS to reimburse dispensers for fees and other direct costs of transmitting the required information. This could include dispenser computer hardware and software, as well as dispenser staffing costs. Information is not available to DHSS to estimate this cost.

Based on recent discussions with the industries affected, the dispensers who will qualify for reimbursement for transmittal costs will fall into three categories - pharmacies, ambulatory surgical centers, and individual practitioners. Each transmission is expected to cost \$0.25. The number of transmissions is expected to grow three percent annually and is reflected below:

ASSUMPTION (continued)

Each dispenser is expected to invoice quarterly for a total of 29,864 (7,466 X 4) invoices annually. It is assumed the database will become operational in January 2018 (FY 2018) and that DHSS will begin receiving invoices in the second half of FY 2018 according to the following schedule. Invoices will be received throughout the full year of FY 2019. DHSS would also be required to hire staff in both the Division of Administration (DA) and the Division of Regulation and Licensure (DRL) to process invoices received from dispensers.

Category	Number Statewide	FY 2018		FY 2019	
		Transmissions (Jan-June 2018)	Reimbursement	Annual Transmissions	Reimbursement
Pharmacies	1,348	6,150,250	\$1,537,563	12,669,515	\$3,167,379
Ambulatory Surgical Centers	101	124,230	\$31,058	255,914	\$63,979
Individual Practitioners	6,017	740,060	\$185,015	1,524,524	\$381,131
Totals	7,466	7,014,540	1,753,636	14,449,953	\$3,612,489

Based on current department practices, each invoice will take 10 minutes to process in DRL and 10 minutes to process in DA. Three different job categories will work together as follows to pay an invoice: in DRL, an Office Support Assistant (\$22,932 annually) will take 2 ½ minutes to open the invoice, log it into the tracking system and forward it to the Account Clerk II. In DRL, an Account Clerk II (\$25,572 annually) will take five minutes to determine and assign the account coding and forward to the Accountant I for review and approval. In DRL, the Accountant I (\$30,672 annually) will take 2 ½ minutes to verify the coding and funding availability and approve the document for central processing. In the DA, an Office Support Assistant will take 2 ½ minutes to open the invoice and distribute it to the Account Clerk II. This position is also responsible for filing the documents after the payment processing is complete. In DA, the Account Clerk II will take five minutes to review, audit and enter the payment documents from DRL in SAM II. In DA, the Accountant I will take 2 ½ minutes to apply final approval to the payment. The additional FTE required for invoice processing is as follows:

29,864 invoices X 20 minutes per invoice = 597,280 minutes to process invoices. 597,280 minutes / 60 minutes per hour = 9,955 hours. 9,955 hours/2,080 = 4.79 FTE (rounded to 5), broken down as follows:

ASSUMPTION (continued)

Job Title	Percent of Time	DRL FTE	DA FTE	Salary	Total Annual Salaries
Office Support Assistant	25	0.625	0.625	\$22,932	\$28,655
Account Clerk II	50	1.25	1.25	\$25,572	\$63,930
Accountant I	25	0.625	0.625	\$30,672	\$38,340
Totals	100	2.5	2.5		\$130,935

It is assumed these positions will be hired on January 1, 2018.

In summary, the DHSS assumes the proposal would have costs to Donated Funds of \$868,825 in FY 2017; \$2,830,710 to Unknown in FY 2018; and \$4,608,539 in FY 2019.

Oversight notes, per sections 195.453.1 and 195.475.5, that DHSS is not allowed to incur additional expenses that would be charged as an expense to the state or hire additional staff to implement the act. All expenses have to be paid by gifts, grants and donated funds and DHSS is required to implement the pilot project using existing staff. Oversight assumes the DHSS would have to receive assurance of donated funds or grant monies prior to implementing the provisions of this proposal would be implemented using current staff.

For fiscal note purposes, the proposal would have no net fiscal impact because: 1) the Prescription Drug Monitoring Program does not receive sufficient funds to cover DHSS costs and is not implemented or 2) program donations and gifts are sufficient to cover the anticipated costs and income and expenditures net to \$0.

Oversight notes section 195.465 provides that the DHSS can assess administrative penalties on dispensers that knowingly fail to submit dispensation monitoring information or that knowingly submit incorrect information. It is assumed that the number and amount of administrative penalties is unknown. For fiscal note purposes, Oversight is not presenting these administrative penalties.

Support from the **Office of Administration (OA), Information Technology Services Division (ITSD)** will be needed for DHSS to establish and maintain an application to monitor the prescribing and dispensing of schedule II, III and IV controlled substances by all professionals licensed to prescribe or dispense such substances in this state. Each dispenser will submit to DHSS, in electronic format, the required information in accordance with transmission standards

ASSUMPTION (continued)

established by the American Society for Automation in Pharmacy, or any successor organization, and shall report data within every seven days. A paper form alternative must be available for those provided a waiver for electronic submission by DHSS.

Infrastructure costs have been calculated using the FY 2015 SDC (State Data Center) CAP (Cost Allocation Plan) document. ITSD costs assume the use of an application built for the State of Missouri and hosted in the SDC, as well as three servers to include development, testing and production of the application, with 100gb of disk storage for each. ITSD estimates total IT consultant costs, related expenditures, and on-going expenses to be \$736,201 for FY 2017; \$416,467 for FY 2018; and \$219,307 for FY 2019.

In response to the previous version of this proposal, officials from the **Office of State Public Defender (SPD)** stated, for the purpose of this proposed legislation, the SPD cannot assume that existing staff will provide competent, effective representation for any new cases where indigent persons are charged with the proposed new crimes relating to dispensation of pharmaceuticals monitoring.

While the number of new cases (or cases with increased penalties) may be too few or uncertain to request additional funding for this specific bill, the SPD will continue to request sufficient appropriations to provide effective representation in all cases.

Oversight assumes the SPD can absorb the additional caseload that may result from this proposal.

Officials from the **Office of Attorney General** note that Section 195.465.1 provides that dispensers who knowingly fail to submit information or knowingly submit incorrect information shall be subject to an administrative penalty and may appeal the penalty to the Administrative Hearing Commission. The AGO assumes this will result in an increase in its caseload. Without knowing the number of resulting appeals, the AGO assumes any potential costs arising from this proposal can be absorbed with existing resources. If there is a significant increase in the number of referrals, or if multiple provisions pass, the AGO may seek additional appropriations.

Officials from the **Office of Administration (OA), Administrative Hearing Commission** anticipate this legislation will not significantly alter its caseload. However, if similar bills pass resulting in more cases, there could be a fiscal impact.

Officials from the **Department of Corrections (DOC)** state penalty provisions for violations, the component of the proposal to have potential fiscal impact for the DOC, is for a class A misdemeanor. The DOC would not supervise these class A misdemeanor cases and so would not have a fiscal impact.

ASSUMPTION (continued)

Officials from the **Department of Insurance, Financial Institutions and Professional Registration**, the **Department of Mental Health**, the **Department of Public Safety, Missouri State Highway Patrol**, the **Joint Committee on Administrative Rules**, the **Office of Administration, Division of Purchasing and Materials Management**, and the **Office of State Courts Administrator** each assume the proposal would not fiscally impact their respective agencies.

In response to the previous version of this proposal, officials from the **Missouri Office of Prosecution Services** assumed the proposal would have no measurable fiscal impact on their organization.

<u>FISCAL IMPACT - State Government</u>	FY 2016 (10 months)	FY 2017	FY 2018	Fully Implemented (FY 2019)
GENERAL REVENUE FUND				
<u>Transfer-Out - SOS</u>				
Reimbursement of local election authority election costs if a special election is called by the Governor	\$0 or (<u>More than \$7,100,000</u>)	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>
ESTIMATED NET EFFECT ON THE GENERAL REVENUE FUND	<u>\$0 or (More than \$7,100,000)</u>	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>

FISCAL IMPACT - Local
 Government

	FY 2016 (10 months)	FY 2017	FY 2018	Fully Implemented (FY 2019)
LOCAL ELECTION AUTHORITIES				

Transfer-In - Local Election
 Authorities

Reimbursement of election costs by the State for a special election	\$0 or More than \$7,100,000	\$0	\$0	\$0
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Costs - Local Election
 Authorities

Special election	<u>\$0 or (More than \$7,100,000)</u>	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>
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**ESTIMATED NET
 EFFECT ON LOCAL
 ELECTION
 AUTHORITIES**

\$0 \$0 \$0 \$0

FISCAL IMPACT - Small Business

If this proposal is implemented, it will have an administrative impact on small business drug dispensers.

FISCAL DESCRIPTION

This proposal establishes the Prescription Drug Monitoring Program Act. In its main provisions, the proposal: (1) Requires the Department of Health and Senior Services to establish and maintain a program to monitor the prescribing and dispensing of all Schedule II through Schedule IV controlled substances by all licensed professionals who prescribe or dispense these substances in Missouri. All funding for the program must be from gifts, grants, and donations; (2) Requires each dispenser to electronically submit specified information to the department for each prescription in accordance with transmission standards established by the American Society for Automation in Pharmacy, or any successor organization, and to report data within seven days;

FISCAL DESCRIPTION (continued)

(3) Allows the department to issue a waiver to a dispenser who is unable to submit the required information electronically; (4) Requires the department to reimburse each dispenser for the fees and other direct costs of transmitting the required information; (5) Requires all submitted prescription information to be confidential and not subject to public disclosure under the Open Meetings and Records Law, commonly known as the Sunshine Law, with specified exceptions. The department must review the dispensation information and, if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, must notify the appropriate law enforcement or professional regulatory entity and provide dispensation information required for an investigation. A person authorized to have dispensation monitoring information who knowingly discloses the information or who uses the information in a manner and for a purpose in violation of these provisions will be guilty of a class A misdemeanor; (6) Requires the department to maintain a registry of persons who it has reasonable cause to believe may have violated the law or been in breach of professional standards. Any person identified must remain on the registry for a minimum of three years; (7) Allows the department to release non-personal, general information for statistical, educational, or research purposes after removing any identifying information; (8) Authorizes the department to contract with any other agency of this state or any other state with a private vendor or any state government that currently runs a prescription monitoring program; (9) Specifies that a dispenser who knowingly fails to submit required dispensation monitoring information to the department or knowingly submits incorrect dispensation information will be subject to an administrative penalty in the amount of \$100 for each violation.

The bill contains a referendum clause.

This legislation is not federally mandated, would not duplicate any other program and would not require additional capital improvements or rental space.

SOURCES OF INFORMATION

Office of Attorney General
Department of Health and Senior Services
Department of Insurance, Financial Institutions and Professional Registration
Department of Mental Health
Department of Corrections
Department of Public Safety -
Missouri State Highway Patrol
Joint Committee on Administrative Rules
Missouri Office of Prosecution Services

SOURCES OF INFORMATION (continued)

Office of Administration -
 Administrative Hearing Commission
 Division of Purchasing and Materials Management
Office of State Courts Administrator
Office of Secretary of State
Office of State Public Defender



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